Exhibit 17

State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al., Civil Action No. 03-11226-PBS

Exhibit to the November 25, 2009 Declaration of Philip D. Robben in Support of Defendants' Joint Motion for Partial Summary Judgment

FINAL STATEMENT OF REASONS

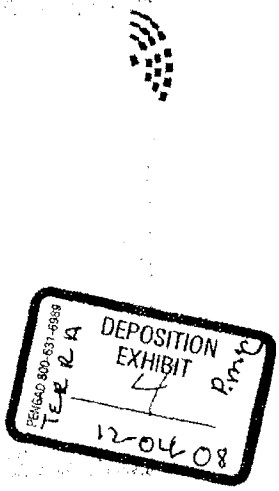
The Medi-Cal program relies in large part upon federal financial participation (FFP) to carry out its mandate to provide a comprehensive program of health care to its beneficiaries. Annually, in the Budget Act, the Legislature reminds the program that services can be provided to the extent that FFP is available.

The former reimbursement formula for prescribed drugs involved pricing comparisons (for the ingredient cost component of dispensed prescriptions) of Estimated Acquisition Cost (EAC), Maximum Allowable Ingredient Cost (MAIC) and Maximum Allowable Cost (MAC). Medi-Cal is mandated to calculate reimbursement on the basis of the lowest of the above, but not to exceed the charge to the general public. Of the three terms identified above, MAC identifies a federal price-of-drugs limit per 42 CFR, 447.331 and 447.332. The Medi-Cal program relies substantially on the federal price of drug limits to contain program costs and has budgeted future fiscal needs recognizing such limits.

However, effective October 29, 1987, two significant events occurred: (1) the existing federal MAC program was dissolved by virtue of its being superseded; and, (2) a new successor federal reimbursement limiting program became effective (42 CFR, Part 447). Failure to act would be hazardous since reimbursements for drugs, now federally price controlled, would increase.

Further, failure to act would place the Medi-Cal program out of compliance with the new federal regulations regarding upper limits of reimbursement for certain multiple source drugs, seriously jeopardizing the amount of FFP available to reimburse providers for all drugs. The combined effect of such a reduction in FFP and unforeseen increase in drug program expenditures could necessitate reductions in services and/or reimbursement provided under the Medi-Cal program, thus reducing the availability of medically necessary services to beneficiaries.

The necessity for this amendment is not readily apparent from the nature of the changes proposed. While appearing to be editorial clean-up, the regulation change allows, by virtue of the regulation adoption procedure, an opportunity to place into the public record the basis of the federal methodology change for reimbursement limits.



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The new federal FFP limitation is on the aggregate amount paid for the 281 drug type codes listed, and not on each individual drug type code. For 19 of the 281 drug type codes subject to Federal Allowable Cost (FAC), the Department already has in place state MAIC limitations which are lower than the new FAC limitations for those drug type codes. The additional savings from these MAIC limitations allows the Department some latitude in implementing the FAC limitations without exceeding the aggregate amount for which FFP is available.

Therefore, in order to lessen any adverse impact of the FAC limitations on pharmacy providers, the Department has decided to apply the new federal price limits only to those drug products which are determined to be available to pharmacy providers at or below the FAC price. Section 51513 (a) (12) has been amended to provide that drug products are "available" where at least one regional wholesaler regularly carries the drug at an Average Wholesale Price (AWP) at or below the FAC price.

Application of this standard will insure that California pharmacists can actually obtain such drug products at an AWP which is at or below the FAC price. The Department recognizes that obtaining the drug product at such price may sometimes require pharmacy providers to utilize a different wholesaler than the provider usually buys from; however, the Department believes that the important consideration is whether the drug product is available at or below the FAC price. Individual providers may elect to purchase the drug product at or below the FAC price from their regular or another supplier, to purchase it from a supplier at a higher price, to fill the prescription from existing stock which may have been purchased at a higher price, or not to fill the prescription at all. These choices are consistent with those already available to pharmacists generally whether or not FAC prices are the limiting issue.

In adopting this regulation amendment to implement the revised federal upper limits of reimbursement for certain multiple source drugs, the Department is using the following documentation as its basis:

1. Federal regulation change announcement:

   52 Federal Register 28657-8, Federal Register, Vol. 52, No. 147, July 31, 1987.

2. HHS News:

   Released-Friday, July 31, 1987

3. HCFA Publication 45-6 (August 1987, Rev.6)
   State Medicaid Manual, part 6-Payment for Services, Section 6305, "Specific Upper Limits for Multiple Source and 'Other' Drugs".

4. Wholesale Pricing Catalog: *
McKesson Item Catalog, dated October 15, 1986

5. Wholesale Pricing Catalog:
Burgen Brunswig-Alpha listing of generic source items, dated August 28, 1987

6. Wholesale Pricing Catalog:
Anfac Drug Supply-Print-out of items and prices, dated August 30, 1987

7. Wholesale Pricing Catalog:
Pharmaceutical Care Network-1987 Buying Group contract list. Prices quoted April 1, 1987 to March 31, 1988, dated July 28, 1987

8. Wholesale Pricing Catalog:
Geneva Generics, Inc.-AWP, Wholesale and Direct price list, effective July 13, 1987

9. Wholesale Pricing Catalog:**
Goldline Laboratories-Goldline GEN™ Products and Generic Pharmaceuticals Catalog/Price List, dated February 5, 1986. (Updated issue requested, but not available.)

10. Wholesale Pricing Catalog:***
Purepac Pharmaceutical Co.-Generic Products Catalog/Price List, dated October 16, 1986. (Update issue requested, but not available.)

11. Letter of Information:
DHS (Tom Elkin) to California Drug Wholesalers-announcing federal price limits and list of drugs, dated September 25, 1987.

12. Previous federal regulation describing MAC:
Commerce Clearing House, Inc.-Medicaid Regulations, pg.8500 (3-87) 21,891; 21,892; 21,893

* Document used is the August 1, 1987 revision of the October 15, 1986 catalog.

** Document used was superceded by the September 1, 1987 edition, received on October 15, 1987. Goldline's direct prices (minimum order $50) are consistently below the FAC. Goldline's suggested wholesaler prices (AWP) are variable as to FAC and are discounted by suppliers making comparisons difficult.

*** Document used was superceded by the August 10, 1987 edition, received on October 25, 1987. Purepac's prices were generally at or below FAC, but some were higher.

Brief Summary of Testimony Presented at Public Hearing on January 6, 1988 and Correspondence Received by the Department, the Department's Comments, Decision, and Basis.

Public Hearing

There were 14 persons who presented testimony at the public hearing.

Testimony:

One speaker, Mr. Drake Nakaisai, representing Merck, Sharpe, and Dohme (MSD), a drug manufacturing firm, supported the upper limits of reimbursement even though the limits adversely affected a major drug product sold by MSD.

DHS Comment:

The Department appreciates the positions of MSD in support of cost-savings measures.

Testimony:

Another speaker, Mr. Robert Rodgers, representing Professional Pharmaceutical Advocates, claimed the regulation was adopted illegally as an emergency measure.

DHS Comment:

The Department, having conferred with house counsel and having conferred with the Office of Administrative Law in the preparation of R-84-87, is confident it is on sound legal grounds regarding the regulations.

Testimony:

The remaining 12 persons presenting oral testimony all addressed a single issue, the switching of brands on anticonvulsant drugs. The central focus was only one drug, Carbamazepine. The contension by all speakers, each presenting personal anecdotal testimony of therapeutic failures, was that interchanging of brands was the cause of alleged therapeutic failures. Notwithstanding the fact that such alleged failures occurred prior to adoption of this regulation, the testimonials suggest that the regulation amendment was ill-conceived and will lead to further clinical failures. They also concluded that brands of anticonvulsant drugs should not be changed without the knowledge and consent of the patient's attending physician.

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DHS Comment:

The Department is aware of and sensitive to the issue raised by public presenters. This issue is addressed by the regulation on two levels. First, the United States Food and Drug Administration (FDA), in exercising its responsibility to review multiple source drugs for therapeutic equivalence, has published in its publication: "Approved Drug Products with Therapeutic Equivalance", a designation of "AB" for all drug products of concern to the public presenters. "AB" means that a drug products meets the necessary bioequivalence requirements to be considered therapeutically equivalent to other pharmaceutically equivalent products. As such, these drug products are considered brand interchangeable by the FDA and by the Health Care Financing Administration (HCFA). California's Department of Health Services (DHS) agrees with the Federal Government.

Second, both federal authorities and the State DHS recognize that individual patients may, for unclear reasons, achieve a higher level of clinical success on one brand of an equivalent drug than another brand. Accordingly, the federal regulations and the State-implementing regulations provide a mechanism to allow a physician to specify a brand that is medically necessary for a patient. An internal audit of the Medi-Cal system has verified that the upper reimbursement limit override mechanism is operational and satisfactory. No patient who, for whatever reason, has a bonafide medical need for a specific brand of a drug will be denied access to that brand due to this regulation.

Testimony:

The California Pharmacists Association (CPhA) presented written testimony questioning the basis for emergency filing for these regulations. Among the comments made by CPhA were: issue taken regarding the impact on small business; reference to CPhA's Pharmaceutical Care Network (PCN) contract prices and use of certain other price reference sources; clarity of the term "regional California drug wholesaler"; omission of a special condition for prior authorization; and, the need for an adequate dispensing fee.

DHS Comments:

As stated earlier, the Department is confident it has strong legal foundation for filing this regulation change on an emergency basis. Also, as stated elsewhere, there is no adverse fiscal impact on small business since the drug products dispensed are reimbursed under the standard formula for prescription drug reimbursement, as no second tier reimbursement formula exists.

As to the price reference sources relied upon, the asterisks and footnotes earlier in this document in the reference listing reduce to writing the clarifications verbally communicated to CPhA several months

ago. At that time, the verbal clarifications were adequate and understood.

Regarding the use of CPhA's PCN contract price list as a reference, its purpose was simply to highlight the fact that well over 2,500 small community pharmacy practices, about one-half of the pharmacy practices in California, have access to the multiple source drug products at reduced contract prices which, in some cases, are substantially below the upper limits of reimbursement. While the PCN is a membership buying group, no small practice (up to 15 stores per owner) is precluded from joining and the enrollment fees are within the reach of even the smallest of practices (CPhA member: $400, non-CPhA member: $800). Its use as a reference is not to imply that Medi-Cal's reimbursement rates are based at the PCN contract prices but rather to underscore availability. Organizations larger than 15 stores under one ownership are not small businesses; and, by virtue of their size, they have their own purchasing leverage to achieve savings in their purchases from wholesalers and manufacturers.

Regarding clarity of the term "regional California drug wholesaler", the term is common among members of the retail pharmacy community. Indeed the phrase is in concert with the dictionary definitions of the words singly and as the parts of a phrase. A "regional California drug wholesaler" is one who distributes drugs from a facility in California to a client base within a geographic region of California. This is to say the business activities are neither localized to a small area, e.g., a city or parts thereof, nor are such activities so broad in scope that services are rendered to the entire state from a single wholesaler facility. A number of California drug wholesalers meet the definition, including but not limited to, the various facilities of each of McKesson Drug Company, Bergen-Bruswig Drug Company, and Amfac Drug Company. CPhA is aware of such a definition and has an understanding as has virtually every pharmacist in practice in California. The term is neither new, nor unclear, to its intended affected group. Accordingly, a specific definition reference is unwarranted.

Regarding Section 51513 (a) (14), the Department acknowledges and agrees in principle with CPhA's points regarding the basis for prior authorization to override the price ceilings for temporary shortages of FAC drug products. However, such problems are not as commonplace as characterized by CPhA. The Department already has under consideration a "regulation clean-up package" which addresses several related policy matters, including the aforementioned item. A language change at 51513 (a) (14) to allow solely for the hypothetical temporary problem in available inventory that is less than statewide in scope would be premature if done as part of R-84-87. The Department appreciates the additional language as suggested by CPhA, and will take the suggestions into consideration for inclusion in the "regulation clean-up package". In the interim period, the Department will deal with the issue on a

case-by-case basis. In the first two months of activity for R-84-87, there has been such a problem with just one drug and only one complaint about it. The problem was handled on the one-case basis to everyone's satisfaction, including CPhA. The Department rejects the notion that the omission of the price override provision somehow causes the regulation to fail any "clarity" standard. Reasons for approval of Treatment Authorization Requests are a matter of professional judgment, not a list of items or conditions that, if met, are automatically authorized.

As to the pharmacy dispensing fee concerns expressed by CPhA, the Department counters that the Medi-Cal pharmacy dispensing fee is reasonable both in terms of meeting the federal intent at 42 CFR, Part 447, and in comparison to other states' Medicaid dispensing fees. California (Medi-Cal) ranks seventh nationally among all the Medicaid agencies as to level of dispensing fee allowed. It would be counterproductive and inimical to the intent of the federal regulations for ingredient cost savings, accrued by fostering the dispensing of lower cost multiple source drugs, to be transferred into higher fees. The Department rejects the notion that it has failed to consider the adequacy and reasonableness of the dispensing fee while adopting this regulation. The Department further rejects the notion that the availability of medically necessary services to beneficiaries will be compromised due to the present Medi-Cal dispensing fee when linked to this regulation amendment. The actual reimbursement formula, based on the state's definition of estimated acquisition cost plus a fixed dispensing fee, has not changed. To the degree that such a formula is satisfactory to providers absent this regulation amendment, it is satisfactory with the regulation amendment. The Department has received no complaints whatsoever on this issue.

Brief Summary of Letters

The Department and the Governor's Office received several letters and telegrams related to R-84-87. There were approximately 85 letters from interested citizens (lay persons), approximately 130 letters from interested physicians, 3 letters from medical associations, approximately 6 letters from disease support groups, and approximately 150 telegrams from interested pharmacists. While regulation amendment package R-84-87 affected over 280 different drug items, all correspondence, without exception, concerned only 1 category of drugs, the anticonvulsants. There are three anticonvulsant drug items affected by R-84-87. They are: carbamazepine, 200mg tablets, valproic acid, 250mg capsules, and primidone, 250mg tablets. The specific focus of all the correspondence was carbamazepine, 200mg tablets.

The letters carried a single theme; that is, they expressed concern over brand switching of medication without the knowledge and approval of the attending physician. None of the letters suggested that the various brands of drugs which are available at or below the federal upper limit

of reimbursement were ineffective or unsafe; rather, they expressed concern that switching from one brand of a drug to another brand of the same drug might result in a therapeutic failure. Some letters provided an anecdotal example of former therapeutic failures, allegedly due to brand switching. In no case was an alleged therapeutic failure documented by a valid scientific study of any drug products marketed in the United States. Clinical observations appeared to be the only authenticating basis for the allegations.

DHS Comments:

Since the correspondence carried so uniform a theme it was evident that they were the result of a letter writing campaign. With regard to the telegrams sent both to the Department and to the Governor's Office, all carried exactly the same text, word for word. DHS inquiry discovered that they were prepared and sent by a McLean, Virginia advertising firm, Targeted Communications. Targeted's client for this project was the drug company, Ciba-Geigy Corporation of Ardsley, New York. Ciba-Geigy is the innovator and major distributor of the anticonvulsant drug, Carbamazepine, 200mg tablets. The wholesale price of their drug product, Tegretol™ (Carbamazepine, Ciba-Geigy) is above the federal limit of reimbursement. Since the true source of the telegrams was a single company and not various signatories including Mr. "no name", the telegrams were not responded to individually by the Department. Ciba-Geigy has separately corresponded with the Department and the Department has responded. Both communications are a part of the record for R-84-87. This exchange of correspondence was deemed adequate to address the concerns expressed in the telegrams.

The letters from concerned lay persons, physicians, support groups, and medical associations were individually authored; but again, carried a single theme. All were responded to by the Department. The Department's response to the writers included the reason that Medi-Cal was adopting upper limits of reimbursement for certain multiple source drugs, i.e., federal mandate to the states limiting FFP for Medicaid expenditures. Also included in the Department's response was the basis for assurance of drug product therapeutic equivalence; namely, the FDA designation of "AB" for all affected drug products as described earlier. Lastly, all responses addressed the situation where a patient requires a specific brand of a drug to achieve a positive therapeutic outcome. It was explained that a physician may, for medical necessity, specify a particular brand of a drug. Having done so within the proper manner, the pharmacy claim for payment to Medi-Cal would be adjudicated to appropriate reimbursement for the drug product dispensed.

It is significant to comment that no other drug manufacturing company producing brand name or generic anticonvulsant or other drugs affected by R-84-87 has elected to express concern over the regulation amendment either directly or indirectly via a write-in campaign.

Department's Decision:

The Department has decided to adopt the language presented in the regulation amendment package, R-84-84 without change.

Basis of Department's Decision:

The Department has been required by federal mandate to limit reimbursement for certain multiple source drugs or suffer a loss of FFP which would result in a possible reduction in the availability of medically necessary services to beneficiaries thereby endangering the public peace, health, or safety. The Department has relied upon a published list of drugs subject to reimbursement limitations prepared by the federal HCFA. The Department has relied upon the FDA designation and listing of drug products as "AB", therapeutically equivalent, for all affected drug products. This designation assures that such drug products are, in fact, brand interchangeable. Finally, as to specific brands required by patients for medically necessary reasons, the Department has not only included the necessary language to allow price limit override, but has conducted an internal audit of the mechanisms used to accomplish such overrides and is confident that the system works properly.

No alternative to the upper limits of reimbursement for multiple source drugs which would preserve the state's FFP for Medi-Cal expenditures was offered by any party. The CPhA alternative to transfer ingredient cost savings into dispensing fee increases was rejected as inimical to the purpose of the regulation amendment.

No objection to the price limits per se except for those related to anticonvulsant drugs was received by the Department. The objections received by the Department regarding anticonvulsant drugs were not based upon sound scientific evidence and appeared to be generated by a single manufacturer intent on preserving its market share of the Medi-Cal volume of drugs dispensed to patients.

The Department has determined that no alternative considered would be more effective in carrying out the purpose for which this action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

The Department has determined that the proposed regulations would not impose a new mandate on school districts or other local agencies which must be reimbursed pursuant to Section 17500 et seq. of the Government Code.

The Department has also determined that the proposed regulations would not have a significant adverse economic impact on small businesses.

ADDENDUM TO FINAL STATEMENT OF REASONS

Additional Summarized Written Testimony Presented At Public Hearing On January 6, 1988 and The Department's Comments

Testimony:

Presenter Robert Rodgers also submitted written testimony suggesting the emergency regulation procedure was illegal and unconstitutional. In summary, the written material addressed concerns in seven areas as follows:

1. Drug product selection by pharmacists when dispensing multiple source drugs is frustrated by this regulation;

2. The regulation interferes with the provision of health services because of the upper limits of reimbursement;

3. The regulation violates the negative generic drug formulary in some way;

4. The regulation violates the constitutional right of privacy;

5. The regulation has an impact upon small business;

6. The regulation is arbitrary and capricious on its face;

7. The regulation is arbitrary and capricious because the products on the HCFA list are not available; and,

8. The regulation is arbitrary and capricious as an endangerment to the health, safety and welfare of Medi-Cal recipients.

The written testimony included, as exhibits, letters from a variety of persons as supplements to the testimony. It is notable that the copies of letters to the Department from physicians which are appended as exhibits to this testimony are not accompanied by the Department's replies.

DHS Comment:

The written testimony and appended materials were reviewed thoroughly and given careful and serious consideration. The Department rejects the claim of illegal and unconstitutional adoption of emergency regulations. Below, in the same number order as presented, are the Department of Health Services (DHS) comments on the major points raised:

1. There is no loss of prerogative of the pharmacists' drug product selection rights. The regulation simply establishes an upper limit of reimbursement for any drug product selected and dispensed by the pharmacist. If the selected brand has an AWP at or below the limit, it can be reimbursed by Medi-Cal at the AWP. If the AWP exceeds the limit the pharmacist has the choice of accepting lower reimbursement, requesting a limit override for higher reimbursement, or refusing to render the service. Those same choices exist within the Medi-Cal drug program apart from these regulations. The regulation does not demand "blanket substitution", does not supercede or violate a physician's order to "do not substitute", nor does it set a new standard of documentation for medical necessity beyond that already established in current regulations, both federal and State.

2. The very citations used to point out the regulation as illegal are, in fact, generally relied upon as citations for just the reverse! Medicare and Medicaid do not interfere with providing health services; indeed, the programs facilitate the provision of services by making more effective use of funds available for payment for such services to persons who otherwise might not be able to afford care. Further, the regulations do not provide for any dispenser of drugs other than licensed pharmacists; accordingly, the regulations are upholding the State Medical Practice Act and Pharmacy Practice Act.

3. The State's "negative generic drug formulary" contains none of the drugs subject to this regulation. Additionally, a higher authority, the federal FDA, has determined and published officially that each and every one of the drugs on the HCFA list have drug products available which are brand interchangeable (designated rating of "AB").

4. As stated earlier, there is no forced substitution intended or applied by this regulation. The claim of violation of privacy is without basis or merit.

5. The claim of adverse fiscal impact upon small business is specious. The reimbursement formula for pharmacy claims to Medi-Cal remains unchanged. The regulation encourages pharmacists to select from among available alternatives, the drug product which meets the patients needs and is available within the upper limit. Lower priced generic brands frequently carry a higher margin of profit in comparison to the more costly name brand drug products they compete with. This has the effect of increasing the actual net profit dollars on a smaller gross sale.

   For example, a prescription for 100 tablets of Mellaril® (Thioridazine, Sandoz), 50mg per tablet, which does not carry the physician statement: "Brand medically necessary", may be filled with a therapeutically equivalent drug product (a generic brand).

The AWP for 100 tablets of the Sandoz drug product is $28.32. The federal upper limit is $13.43, which encourages the pharmacist to select a drug product to dispense which is average wholesale priced at or below that level. The current issue of Medi-Span Generic Buying Guide lists 16 drug products, all "AB" rated, as choices for the pharmacist.

(a) Assume the following:

(1) The generic drug is purchased in 1000's rather than 100's due to lower cost.

(2) The pharmacy is one of over 2,500 California pharmacies who are members of California Pharmacists' Association (CPhA) Pharmaceutical Care Network (PCN), a discount buying group.

(3) Routine purchases (other than PCN drugs) from the wholesaler carry a 8% discount.

(b) The Nellaril-filled prescription would show:

Cost of drug at AWP ($28.32) less 8%:	$26.05	(purchased in 100's)
Pharmacy dispensing fee:	+4.05	
	$30.10	
FAC limited allowance:	-17.48	(includes disp. fee)
transaction loss =	<$12.62>	(if brand name drug disp)

(c) The generic brand-filled prescription would show:

Cost of Goldline brand drug under PCN is $ 5.23 when purchased in 1000's.

AWP of Goldline brand drug product:	10.90	(used by Medi-Cal for reimbursement formula)
Pharmacy dispensing fee:	+4.05	
	$14.95	
Medi-Cal payment amount =	$14.95	(AWP+fee is below FAC)

(d) Ingredient reimbursement over AWP of generic drug product $10.90 (AWP) - $5.23 (actual cost) = $5.67.

(e) Ingredient reimbursement over AWP of brand name product, if not limited by FAC: $28.32 (AWP) - $26.05 (actual cost) = $2.27.

The example shows that, in addition to the $4.05 dispensing fee, the generic brand-filled prescription offers a $3.40 margin of profit over the brand name product in the absence of this regulation. The FAC limits, of course, make the dispensing of the brand name product economically impractical. The points are two:

(i) Generic dispensing is attractive to the pharmacist because the margin in actual dollars is greater than for brand name dispensing and these increased profit dollars are achieved on a smaller gross sale which means less invested in inventory; and,

(ii) Therapeutically equivalent generic brands are available in the marketplace from which the pharmacist may select his choices.

The above example certainly does not represent all transactions, but does illustrate the alternatives in the marketplace. Not only did the pharmacist increase his margin by $3.40 when dispensing the generic drug product over the brand name product; but, by placing an upper limit of reimbursement, Medi-Cal saved $15.15, which is more than 50% of the reimbursement amount for the brand name product.

6. The written testimony attempts to use the introduction statements in FDA's Orange Book and other writings as validations that FDA has not judged certain drug products as brand interchangeable. A statement that the FDA did not intend the Orange Book to be the basis for brand interchange is to misunderstand the entire subject. The Orange Book has NO OTHER PURPOSE other than to identify interchangeable brands of multiple source drugs. The official title of the book indicates, "Approved Drug Products with Therapeutic Equivalence Evaluations". Accordingly, the Department rejects the charge of "Arbitrary and Capricious Upon Its Face" as being improper and lacking foundation in fact.

7. The written testimony again charges arbitrariness and caprice, this time regarding drug availability. The drugs are available. A minimum of three drug products, "A" rated by FDA, marketed at or below the federal upper limit of reimbursement are required to achieve placement on the list. The additional standard of regional availability is required in this regulation. Accordingly, the regulation is neither arbitrary nor capricious as it was promulgated after careful, deliberate and serious consideration to the issue of drug product availability. The scenario described by the testimony illustrates a basic misunderstanding of the drug distribution chain as it exists today. This regulation neither creates nor resolves inventory shortages in any particular location. It does, however, protect pharmacy providers from general availability problems at or

below the federal upper limit of reimbursement by retaining the ability to exempt a drug from the upper limits for true availability problems; e.g., all drug products below the upper limits experience a price increase so that none are below the upper limits.

8. The final charge of arbitrary and capricious action relates to a danger to the health, safety, and welfare of Medi-Cal recipients. The Department rejects the notion of arbitrary and capricious rulemaking. Full, careful, serious and deliberate consideration of the health, safety and welfare of Medi-Cal recipients was given prior to promulgating this regulation. The presenter introduced letters (contained in Exhibit C of the written testimony, absent the Departmental response) as evidence of arbitrariness and caprice. Had the responses been included in the Exhibit, it would have been clear that these health and safety considerations were made when promulgating this regulation. The Department can only wonder why the presenter elected not to include the Departmental responses to their example letters. Nonetheless, the response letters are in the rulemaking file as introduced by the Department. As such, they address this health and safety concern.

Testimony:

Presenter Frederick S. Mayer also submitted written testimony suggesting the regulation was improperly adopted as an emergency, is illegal, and that its adoption will have an adverse impact on patients and small business.

The written testimony describes at length reasons why the regulations are not justified as emergency measures. It also describes a set of reasons why the regulations affect small business and Medi-Cal patients.

DHS Comment:

The written testimony presents issues and supporting arguments regarding the emergency nature of the regulations and the affect upon small business and patients. After full, deliberate, serious, and careful consideration of this testimony, the Department rejects the notion that the regulations are not proper as an emergency and as such, illegal. The Department also rejects the arguments regarding the affect upon small business and patients. Since the Department has addressed these same arguments previously, the Department's rationale is not repeated here.

UPDATED* INFORMATIVE DIGEST

The method of reimbursement to provider pharmacies for prescribed drugs dispensed to Medi-Cal patients is set forth in the California Administrative Code (CAC), Title 22, Section 51513. The reimbursement methodology is applied to Medi-Cal Formulary drugs and to non-Formulary drugs dispensed pursuant to prior approval as required.

This amendment to CAC, Title 22, Section 51513 (a) (12), (13), and (14) would change the nomenclature used to identify the federal upper limits of reimbursement for certain multiple source drugs. While the amendment appears to be editorial in nature, the purpose of the amendment is to implement the new federal methodology (42 CFR Part 447) for establishing upper limits of reimbursement. The current reference is to a federal Maximum Allowable Cost program which will be superseded by the new methodology effective October 29, 1987 (42 CFR 447.332).

* There are no changes to the initial Informative Digest.

CM:bc/3-84-87

FINAL STATEMENT OF SMALL BUSINESS IMPACT

The Department of Health Services has determined that the fiscal impact estimated for this regulation amendment will not have a significant adverse economic impact on small business.

The reimbursement formula for drugs subject to the Federal Allowable Cost (FAC) is the same as the formula for all other drugs, i.e., cost (the lesser of the Estimated Acquisition Cost (EAC), Maximum Allowable Ingredient Cost (MAIC), or FAC) plus the fee for services; or, the charge to the general public, whichever is lower. The drug product dispensed shall have its cost determined to be the EAC used by the Department up to the FAC limit. That is, for drug products whose cost is below the FAC limit, the cost is the EAC (generally, the Average Wholesale Price). The fee for service is, likewise, the same for all prescription drugs.

If the cost is above the FAC limit for a drug product medically necessary for a patient, the price limit can be overriddeo via the prior authorization procedure.

Accordingly, there is no significant adverse economic impact on small business.

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FINAL COMMENT ON ADVISORY GROUP APPROVAL

The Department of Health Services has determined that this regulation amendment is not subject to the requirements of Section 14184 of the Welfare and Institutions Code as to Advisory Group recommendations.

The Federal Allowable Cost (FAC) limits neither add nor delete drugs on the Medi-Cal Formulary. Also, the FAC drug products are not considered to be discriminatorily priced per Section 14053.5 of the Welfare and Institutions Code. The above are the sole areas of responsibility under the law for the Department's Advisory Group, the Medical Therapeutics and Drug Advisory Committee (MT&DAC).

Additionally, since these drug price limits are federally adopted and are not based on a single drug product, the drugs are not subject to review by the Bioequivalency Advisory Panel (BAP) of the MT&DAC. The BAP review drug products for bioequivalence when such drug products are proposed as the basis of limits on reimbursement for state adopted Maximum Allowable Ingredient Costs.

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(1) Amend Section 51513(a)(12), (13) and (14) to read:

(12) ~~Maximum~~ Federal Allowable Cost (MFAC) means the price established for a generic drug type code by the United States Department of Health and Human Services in accordance with Sections 447.331 and 447.332, Title 42, Code of Federal Regulations, for which drug product(s) are available to pharmacies from a regional California drug wholesaler with AWP at or below such price.

(13) Cost of the Drug Product or Medical Supply Product, except in cases of prior authorization as provided in subsection (a) (14), means the lowest of the Estimated Acquisition Cost (EAC), the ~~Maximum~~ Federal Allowable Cost (MFAC), or the Maximum Allowable Ingredient Cost (MAIC) for the standard package size. Provided, however, that the cost of the drug product or medical supply product for any Generic Drug Type Code or Medical Supply Type Code for which a MAIC has not been established in accordance with the Administrative Procedure Act, shall mean the lower of the MFAC or EAC of the drug product or medical supply product dispensed. The EAC, the MFAC and the MAIC shall be updated by the Director no less often than every 60 days for medical supply products and no less often than every 30 days for drug products. In order to reflect the most current price information available, the Director may temporarily update the EAC, or the MAIC, to reflect the price listed for a standard package

in the principal labeler's catalog, or supplements thereto, until such time as the most recent change in price is reflected in the price listed in the Department's primary price reference source, or for products not listed in the Department's primary price reference source, the secondary price reference source.

(14) Cost of the drug product or medical supply product for which Prior Authorization has been granted in accordance with Section 51003, for a drug product or medical supply product having a higher cost than the established MFAC or MAIC, means the EAC of the drug product or medical supply product authorized by the Medi-Cal consultant. Such prior authorizations requests shall be made only upon both the handwritten and signed request of the prescriber and shall contain adequate information to justify the medical necessity for the higher cost drug product or medical supply product and shall contain the following statement: "I certify that in my medical judgment the requested drug product (or medical supply product) is medically necessary."

NOTE: Authority cited: Sections 10725, 14053, 14105, 14105.7, 14124.5, 14132 and 14133, Welfare and Institutions Code; and Statutes of 1982, Chapter 328, Section 57.
Reference: Sections 14103.7, 14105, 14105.7, 14132, 14133 and 14133.1, Welfare and Institutions Code; and Statutes of 1982, Chapter [illegible] Section 53.

ADDENDUM TO FINAL STATEMENT OF REASONS

Additional Summarized Testimony Presented At Public Hearing On January 6, 1988 and The Department's Comments

Testimony:

One speaker, Mr. Frederick S. Mayer, representing Pharmacist Planning Services, Inc., mentioned, as a part of his oral and written testimony, a concern not related to the anticonvulsant drug issue. That concern is for "double inventory" of narcotic drugs. Such "double inventory" increases the exposure to and risk of robbery, according to Mr. Mayer.

DHS Comment:

Mr. Mayer's brief comments about exposure to robbery is an absolute "Red Herring". There is no information whatsoever to logically support such a hypothesis as a result of this regulation change.

Indeed, inventories follow demand. Should a government program's price limit or other "demand modifier" alter the inventory mix, there may be a very short-term increase in total inventory as initial purchases of a second brand are required. However, immediately and as continued usage occurs with each inventory component, a balancing of total inventory results. If this were not true, inventories would grow to infinity as a result of new product introductions in the marketpace. Such does not occur because retail sales influence wholesale purchases, keeping inventories stable. Inventory mixes change constantly, but a quantity of any one component on hand is almost entirely driven by demand.

An argument the Deparmtent could raise (which is more defensible than the "duplicate inventory" theory) is that the robber and the illegal street consumer of stolen drugs prefer, nay, demand the brand name narcotics, as they all have the company logo and product code number embossed on each tablet. This well-known identification policy greatly increases the street value of stolen brand name drugs. Thus, with the introduction of a less well-known generic drug on the shelf (due to government price limits) accounting for a measure of; the inventory, the government price limits "improve" the scenerio and diminish the risk by displacing a portion of the economically more attractive brand name drugs. The pharmacy, in theory, should be less vulnerable to attack by thieves!

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